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| | Filing Date | | 2001-11-15 |
| | First Named Inventor | Holm et al. | |
| | Art Unit | 1644 | |
| | Examiner Name | N. M. Rooney | |
| | Attorney Docket Number | 27554-0007001 | |

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|-----------------------|------------|---|--------------------------|
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| | 2 | WIEDEMANN, P. et al., Molecular and Structural Analysis of a Continuous Birch Profilin Epitope Defined by a Monoclonal Antibody; The Journal of Biological Chemistry, Vol. 271, No. 47, pp. 29915-29921, (1996) | <input type="checkbox"/> |
| | 3 | SMITH, A. M. et al., Localization of antigenic sites on Der p 2 using oligonucleotide-directed mutagenesis targeted to predicted surface residues; Clinical and Experimental Allergy, Vol. 27, pp. 593-599, (1997) | <input type="checkbox"/> |
| | 4 | SPANGFORT, M. D. et al., Three-Dimensional Structure and Epitopes of Bet v 1; International Archive of Allergy and Immunology, Vol. 119, pp. 243-245, (1997) | <input type="checkbox"/> |
| | 5 | HOFFMAN, D. R. , Allergens in Hymenoptera venom XXV: The amino acid sequences of antigen 5 molecules and the structural basis of antigenic cross-reactivity; The Journal of Allergy and Clinical Immunology, Vol. 82, No. 5, pp. 706-716, (1993) | <input type="checkbox"/> |
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| | 7 | TAKAI, T. et al., Engineering of the major house dust mite allergen Der f2 for allergen-specific immunotherapy; Nature Biotechnology, Vol. 15, pp. 754-758, (1997) | <input type="checkbox"/> |
| | 8 | FIEBIG, H., Immunologische Aspekte der spezifischen Immuntherapie (Hyposensibilisierung) Teil I: Die Steuerung de IgE-Synthese; Interdisciplinary Journal of Allergy and Environmental Medicine, pp. 3-12, (1995) | <input type="checkbox"/> |
| | 9 | BLASER, K., Immunologische Grundlagen der allergenspezifischen Immuntherapie, Zentrum Fur Rhinologie und Allergologie; Vol. 35, No. 5, pp. 217-222, (2009) | <input type="checkbox"/> |
| | 10 | KAHLERT, H. et al., Characterization of Hypoallergenic Recombinant Bet v 1 Variant as a Candidate for Allergen-Specific Immunotherapy; International Archives of Allergy and Immunology, Vol. 145, pp. 193-206, (2008) | <input type="checkbox"/> |

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| 11 | STANLEY, J. S. et al., Identification and Mutational Analysis of the Immunodominant IgE Binding Epitopes of the Major Peanut Allergen Ara h 2; Archives of Biochemistry and Biophysics, Vol. 342, No. 2; pp. 244-253, (1997) | <input type="checkbox"/> |
| 12 | SCHRAMM, et al., Sequenzspezifische Mutagenese des Graspollenallergens rPhl p 5b: Allergenvarianten mit reduzierter IgE-Reaktivität, aber konservierter T-Zell-Reaktivität, Mainzer Allergie-Workshop; Interdisciplinary Journal of Allergy and Environmental Medicine, Vol. 7, pp. 24, (1998) | <input type="checkbox"/> |
| 13 | COLOMBO, P. et al., Identification of an Immunodominant IgE Epitope of the Parietaria judaica major Allergen; The Journal of Immunology, Vol. 160, pp. 2780-2785, (1998) | <input type="checkbox"/> |
| 14 | YUSUKE, ABE et al., Epitope Analysis of Birch Pollen Allergen in Japanese Subjects; Journal of Clinical Immunology, Vol. 17, No. 6, pp. 485-493, (1997) | <input type="checkbox"/> |
| 15 | SPARHOLT, S. H. et al., Crossreactivity and T-cell epitope specificity of Bet v I-specific T cells suggest the involvement of multiple isoallergens in sensitization to birch pollen; Clinical and Experimental Allergy, Vol. 27, pp. 932-941, (1997) | <input type="checkbox"/> |
| 16 | LUZZAGO, A. et al., Mimicking of discontinuous epitopes by phage-displayed Peptides, I. Epitope mapping of human H ferritin using a phage library of constrained Peptides; Gene, Vol. 128, pp. 51-57, (1993) | <input type="checkbox"/> |
| 17 | AKI, T. et al., Structure of IgE Epitopes on a New 39-kD Allergen Molecule from the House Dust Mite, Dermatophagoides farinae; International Archives of Allergy Immunology; Vol. 103, pp. 357-364, (1994) | <input type="checkbox"/> |
| 18 | WESLEY BURKS, A. et al., Mapping and mutational analysis of the IgE-binding epitopes on Ara h 1, a legume vicilin protein and a major allergen in peanut hypersensitivity; Eur. J. Biochem., Vol. 245, pp. 334-339, (1997) | <input type="checkbox"/> |
| 19 | GAJHEDE, M. et al., X-ray and NMR structure of Bet v 1, the origin of birch pollen allergy, Nature Structural Biology, Vol. 3, No. 12, pp. 1040-1045, (1996) | <input type="checkbox"/> |
| 20 | SPANGFORT, M. D. et al., Crystallization and Preliminary X-Ray Investigation at 2.0 Å Resolution of Bet v 1, a Birch Pollen Protein Causing IgE-Mediated Allergy; Proteins: Structure, Function and Genetics, Vol. 26, pp. 358-360; (1996) | <input type="checkbox"/> |
| 21 | LU, G. et al., Sequence Analysis and Antigenic Cross-reactivity of a Venom Allergen, Antigen 5, from Hornets, Wasps, and Yellow Jackets; The Journal of Immunology, Vol. 150, No. 7, pp. 2823-2830, (1993) | <input type="checkbox"/> |

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|----|---|--------------------------|
| 22 | IPSEN, H. et al., Specificity mapping of patients IgE response towards the tree pollen major allergens Aln g 1, Bet v 1 and Cor a 1; Clinical and Experimental Allergy, Vol. 22, pp. 391-399, (1992) | <input type="checkbox"/> |
| 23 | FERREIRA, F. et al., Modulation of IgE-Binding Properties of Tree Pollen Allergens by Site-Directed Mutagenesis; Advances in Experimental Medicine and Biology, Vol. 409, pp 127-135, (1996) | <input type="checkbox"/> |
| 24 | SMITH, A. M. et al., Recombinant allergens for immunotherapy: A Der p 2 variant with reduced IgE reactivity retains T-cell epitopes; J. Allergy Clin. Immunol., Vol. 101, No. 3, pp. 423-425, (1998) | <input type="checkbox"/> |
| 25 | FABER, C. et al., Secondary Structure and Tertiary Fold of the Birch Pollen Allergen Bet v 1 in Solution; The Journal of Biological Chemistry, Vol. 271, No. 32, pp. 19243-19250, (1996) | <input type="checkbox"/> |
| 26 | DALUM, I. et al., Induction of Cross-Reactive Antibodies Against A Self Protein By Immunization With a Modified Self Protein Containing a Foreign T Helper Epitope; Molecular Immunology, Vol. 34, No. 16-17, pp. 1113-1120, (1997) | <input type="checkbox"/> |
| 27 | SKOLNICK, J. et al., From genes to protein structure and function: novel applications of computational approaches in the genomic era; Tibtech, Vol. 18, pp. 34-39, (2000) | <input type="checkbox"/> |
| 28 | BLUMENTHAL, M. et al., Definition of an Allergen (Immunobiology); Allergens and Allergen Immunotherapy; pp. 37-50, (2004) | <input type="checkbox"/> |
| 29 | RAO, S., PV. et al., B- and T-cell epitopes of tropomyosin, the major shrimp allergen; Allergy, Vol. 53 (Suppl 46), pp. 44-47, (1998) | <input type="checkbox"/> |
| 30 | AALBERSE, R. C., Ph.D., Molecular mechanisms in allergy and clinical immunology; J. Allergy Clin. Immunol., Vol. 106, No. 2, pp. 228-238, (2000) | <input type="checkbox"/> |
| 31 | KING, T. P., et al., Structure and Biology of Stinging Insect Venom Allergens; International Archives of Allergy and Immunology, Vol. 123, pp. 99-106, (2000) | <input type="checkbox"/> |
| 32 | MULLER, W. D., et al., Mapping of T-cell epitopes of Phl p 5: evidence for crossreacting and non-crossreacting T-cell epitopes within Phl p 5 isoallergens; Clinical and Experimental Allergy, Vol. 28, pp. 1538-1548, (1998) | <input type="checkbox"/> |

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| 33 | SCHRAMM, G. et al., "Allergen engineering": variants of the grass pollen allergen rPh1 p 5b for efficient and safer allergen-specific immunotherapy; Oral Communication - Allergens, FC020, pp. 54-55, (1998) | <input type="checkbox"/> |
| 34 | SUPHIOGLU, C. et al., Molecular basis of IgE-recognition of Lol p 5, a major allergen of rye-grass pollen; Molecular Immunology, Vol. 35, pp. 293-305, (1998) | <input type="checkbox"/> |
| 35 | VALENTA, R., Genetically Engineered and Synthetic Allergen Derivatives: Candidates for Vaccination against Type 1 Allergy; Biol. Chem., Vol. 380, pp. 815-824, (1999) | <input type="checkbox"/> |
| 36 | MIRZA, O. et al., Dominant Epitopes and Allergic Cross-Reactivity: Complex Formation Between a Fab Fragment of a Monoclonal Murine IgG Antibody and the Major Allergen from Birch Pollen Bet v 1; Journal of Immunology, Vol. 165, No. 1, pp. 331-338 | <input type="checkbox"/> |
| 37 | PUNNONEN, J., Molecular Breeding of Allergy Vaccines and Antiallergic Cytokines; International Archive of Allergy and Immunology, Vol. 121, pp. 173-182, (2000) | <input type="checkbox"/> |
| 38 | SPANGFORT, M. D., The Potential Use of Recombinant Allergens for Immunotherapy; J. Allergy Clin. Immunol., Vol. 105, No. 1, Part 2, pp. S169 | <input type="checkbox"/> |
| 39 | LARSEN JORGEN NEDERGAARD et al., Toward a Unifying Theory for the Mechanism of Specific Allergy Vaccination; J. Allergy Clin. Immunol., Vol. 105, No. 1, Part 2, S311 | <input type="checkbox"/> |
| 40 | SINGH, M. B. et al., Genetically Engineered Plant Allergens with Reduced Anaphylactic Activity; International Archives of Allergy and Immunology, Vol. 119, pp. 75-85, (1999) | <input type="checkbox"/> |
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